Re-evaluation Note REV2015-06

Re-evaluation Project Plan for Dimethomorph

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Introduction

In Canada, dimethomorph is under re-evaluation by Health Canada's Pest Management Regulatory Agency (PMRA). The PMRA's pesticide re-evaluation program considers potential risks as well as the value of pesticide products to ensure that they continue to meet standards of modern science and current policies established to protect human health and the environment. Under the authority of section 16 of the *Pest Control Products Act*, the registrant of dimethomorph was notified of the initiation of the re-evaluation of dimethomorph. Following this, the registrant indicated their intention to support all uses included on the labels of commercial class products in Canada. This Re-evaluation Note outlines a project plan and timeline for review, and summarizes the anticipated areas of focus related to the re-evaluation of dimethomorph.

Dimethomorph is a fungicide that has been registered in Canada since 1996. Dimethomorph is currently registered to control or suppress certain foliar diseases on various terrestrial food crops (Use-Site Category 14) as well as on greenhouse (Use-Site Category 6) and outdoor ornamentals (Use-Site Category 27). Terrestrial food crops include *brassica* vegetables, bulb vegetables, cucurbit vegetables, fruiting vegetables, grapes, hops, leafy vegetables and potatoes. The two registered dimethomorph end-use products are formulated as a wettable powder and a suspension, respectively, to be applied by ground or aerial equipment.

The project plan discussed below outlines the anticipated areas of focus and risk assessments required to complete the re-evaluation of dimethomorph. Should additional information become available during the re-evaluation period that affects the regulatory status of dimethomorph, the PMRA will reconsider the areas of focus and risk assessments required. Currently, a proposed re-evaluation decision for dimethomorph is anticipated to be published in 2019.

Re-evaluation Project Plan

Human Health Risk Assessment

The toxicology database for dimethomorph was considered adequate at the time of initial registration. Data generated since the time of the original submission that may impact the hazard assessment (for example, neurotoxicity studies) will be evaluated (Appendix I). Verification of the points of departure used for risk assessments will be undertaken and areas not addressed in the original evaluation will be reviewed (for example, assessment of acute reference dose requirement, requirement for an occupational endpoint of concern for a long-term scenario, and application of the *Pest Control Products Act* factor). Recent scientific literature and incident reports will also be incorporated into the re-evaluation.

Dietary exposure and risk assessments previously conducted to support the registered uses of dimethomorph will be re-evaluated to ensure that they continue to meet standards of modern science and current policies. In particular, the dietary exposure assessment will be updated to reflect current data, including available dimethomorph usage information, drinking water estimated environmental concentrations, current food consumption data, and the incorporation of revised toxicological reference doses, if applicable. The residue chemistry database for the dietary risk assessment is considered to be complete and no additional data requirements are anticipated at this time.

Occupational and non-occupational exposure and risk assessments of dimethomorph will be revised to reflect currently available scientific data and approaches, as well as revised toxicological points of departure, if applicable. In the absence of chemical-specific data, standard defaults will be used in the occupational and residential exposure and risk assessments. Related data requirements include a dislodgeable foliar residue study, which is used for postapplication worker assessments.

Environmental Risk Assessment

Environmental risk mitigation measures will be reviewed to ensure consistency with current label requirements, and the Toxic Substances Management Policy will be taken into consideration.

Value

The value of dimethomorph will be considered. The viability of alternatives will be examined if risks of concern are identified.

Data Requirements

Additional data requirements related to toxicology and occupational exposure have been identified for dimethomorph and were requested from the technical registrant. For details, see Appendix I.

Anticipated Timeline for Re-evaluation

A proposed re-evaluation decision for dimethomorph is anticipated to be published for consultation in 2019.

Additional Information

PMRA documents can be found on the Pesticides and Pest Management section of Health Canada's website. PMRA documents are also available through the Pest Management Information Service: phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra.infoserv@hc-sc.gc.ca.

Appendix I Data Requirements for the Re-evaluation of Dimethomorph

Toxicology

DACO 4.3.5	Short-term Dermal Toxicity
DACO 4.3.8	Short-term Immunotoxicity
DACO 4.5.3	Prenatal Developmental Toxicity (non-rodent)
DACO 4.5.12	Acute Neurotoxicity (rat)
DACO 4.5.13	Subchronic Neurotoxicity (rat)

Occupational Exposure

DACO 5.8	Dermal Absorption
DACO 5.9	Dislodgeable Residues (foliar)